May 23, 2002

MEMORANDUM TO: Jacqueline E. Silber, Deputy Chief Information Officer
Office of the Chief Information Officer

FROM: Ashok C. Thadani, Director **/RA/**
Office of Nuclear Regulatory Research

SUBJECT: COMPATIBILITY OF NRC REGULATORY ANALYSIS GUIDANCE AND OMB INFORMATION QUALITY GUIDELINES

In a Commission Memorandum of April 22, 2002,[1] the staff committed to review NRC regulatory analysis guidance to determine whether NRC's current treatment of uncertainty satisfies the information quality principles being sought by the Office of Management and Budget (OMB). OMB's guidelines focus on the need to consider uncertainty, in the context of quantifying risk, and the need to communicate those findings to the public.

The NRC has long recognized the treatment of uncertainty as crucial in ensuring meaningful regulatory decisions and as such it is an integral and important consideration in NRC's policy and guidance documents overseeing regulatory analyses. There are two primary documents supporting this activity. The first is the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (NUREG/BR-0058, Rev. 3 (RAG). This document focuses on broad policy concepts and thus discussions of uncertainties tend to be more general in nature. However, the RAG consistently refers the reader to more detailed guidance available in the "Regulatory Analysis Technical Evaluation Handbook," NUREG/BR-0184 (RATEH). This document, which complements the RAG, expands upon policy concepts and provides data and methods to support the development of regulatory analyses. Thus for example, Attachments 1 and 2 contain each document's primary discussion on the treatment of uncertainties and provides a good indication of the specificity and detail inherent in each. It should be noted however that other discussions of uncertainty are dispersed throughout these documents.

OMB has identified specific information requirements for the treatment of uncertainties in documents made available to the public in support of regulation. In this regard,
OMB has indicated that with respect to the analysis of risks to human health, safety and the environment, agencies shall either adopt or adapt the quality principles used for the risk information in the Safe Drinking Water Act Amendments of 1996.[2]

Codified at 42 USC 300g-1(b)(3)(A), an agency is directed to use:

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[1] Commission memorandum from William Travers, Draft Federal Register Notice on NRC's Proposed Information Quality Guidelines, April 22, 2002.

[2] U.S. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Section V.3.b.ii.C, Federal Register, Vol. 67, No. 36, February 22, 2002.

> (i) the best available, peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).[3]

Further, section 42 USC 300g-1(b)(3)(B), includes a basic quality standard for the dissemination of public information about risks of adverse health effects. It states that agencies are directed, “to ensure that the presentation of information (risk) effects is comprehensive, informative, and understandable.” Agencies are further directed ...

> in a document made available to the public in support of a regulation [to] specify, to the extent practicable - (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.[4]

RES has reviewed NRC’s existing guidance concerning the treatment of uncertainty, and the Safe Drinking Water Act’s information quality standards. Initial comparisons focused on the specific issues raised under 42 USC 300g-1(b)(3)(B), of the 1996 amendment. This was followed by a summary comparison to the more general characterizations of the information requirements in the Safe Drinking Water Act Amendments. The results of this comparison appear as Attachment 3 to this memorandum. Based on this review, RES concludes that NRC’s guidance on the treatment of uncertainty, as currently provided in the RATEH, is at a level of specificity and completeness that is consistent with OMB’s standards, but that NRC’s policy on the need to communicate these findings to the public is insufficient.

RES, therefore, recommends replacing selected text currently appearing on page 21 of the RAG. The intent of these changes is twofold. First, to make clear to NRC analysts that, to the extent practicable, a full discussion of uncertainties needs to be **presented** in the regulatory analysis and in that way be disseminated to the public. And second, to incorporate certain language in the legislation to remove any ambiguity concerning exactly what needs to be considered and presented. The proposed changes affect the following two paragraphs and all changes appear in bold text.

From Page 21 of the “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission”, Revision 3, July 2000.

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[3] Ibid.

[4] Ibid

Categories of groups affected by the proposed regulatory action should be identified. Groups may include (but are not limited to) the general public, units of State and Local government, Indian tribes, licensees of the NRC and/or Agreement States, employees of licensees, contractors and vendors, the NRC, and other Federal agencies. Within each affected group, further differentiation, for example, **children as a subset of the general population**, may be necessary if the **health and safety implications of the** proposed action affects **that segment of the general population differently or disproportionately**. Under these circumstances, separate estimates and evaluations of values and impacts, **and associated uncertainties**, should, **to the extent practicable**, be made for each distinct category. (Remainder of paragraph unchanged).

Uncertainties are important to consider **and need to be presented** in a regulatory analysis. **To the extent practicable, best available peer reviewed studies, and data collected by accepted or best available methods, should be utilized and discussed. Specifically, expected values, expressions of uncertainty which can be presented in terms of upper- and lower-bounds, and studies, data, and methodologies that support or fail to support the risk estimates must, to the extent practicable, be reported in the regulatory analysis.** Hypothetical best- and worst-case values and impacts can be estimated from sensitivity analyses. Sensitivity analysis can be used in addition to or in lieu of formal uncertainty analysis; the former option should be exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporating uncertainties and sensitivities in a regulatory analysis is in the Handbook.

RES further recommends that these changes to the RAG be made in conjunction with a currently planned Revision 4 to the RAG. That revision, which will provide additional policy on the treatment of individual requirements, is currently scheduled in the September 2002 time-frame.

Attachments:
1. Discussion of uncertainty in Regulatory Analysis Guidelines
2. Discussion of uncertainty in Regulatory Analysis Technical Evaluation handbook
3. Comparison of NRC’s Existing Guidance and the Safe Drinking Water Information Quality Standards

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ATTACHMENT 1

NUREG/BR-0058, REV.3, Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, p.21.

Discussion of Uncertainty

Uncertainties are important to consider in developing a regulatory analysis. The sources and magnitudes of uncertainties in values and impact estimates and the methods used to quantify uncertainty estimates should be discussed in all regulatory analyses. Hypothetical best- and worst-case values and impacts can be estimated for sensitivity analyses. Sensitivity analyses can be used in addition to or in lieu of formal uncertainty analysis: the former option should be exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporating uncertainties and sensitivities in a regulatory analysis is in the Handbook. The Handbook also discusses the distinction between them.

Attachment 2 - Regulatory Analysis Technical Evaluation Handbook, pp. 5.3-5.8

5.4 Treatment of Uncertainty

Chapter 4 of the NRC Guidelines requires that uncertainties be addressed in regulatory analyses, both for exposure and cost measures. In addition, NRC's Final Policy Statement on the use of probabilistic risk assessment (PRA) in nuclear regulatory activities (NRC 1995b) states that sensitivity studies, uncertainty analysis, and importance measures should be used in regulatory matters, where practical within the bounds of the state-of-the-art. Uncertainties in exposure measures, especially those related to facility accidents, have traditionally been difficult to estimate. With respect to power reactor facilities, much has been written about uncertainty analysis in risk assessments. The more rigorous assessments typically provide an uncertainty analysis, usually performed via stochastic simulation on a computer. Briefly, the analyst determines probability distributions for as many of his input parameters as deemed necessary and practical. A computer code then samples values from each distribution randomly and propagates these values through the risk equation to yield one result. When repeated a large number of times (at least several hundred), a probability distribution for the result is generated, from which the analyst can extract meaningful statistical values (e.g., mean, standard deviation, median, and upper and lower bounds for given confidence levels).

Risk assessments for non-reactor facilities often identify best estimates only. Some have provided uncertainty ranges (see Appendix C), but their development has generally been less rigorous than that for reactor facilities. On the positive side, accident scenarios for non-reactor facilities are much less complex than for power reactors, facilitating uncertainty estimation, at least from a calculational perspective.

This Handbook is not intended to provide basic information on probability and statistics, and therefore does not attempt to describe the details of uncertainty analysis techniques. The analyst needing information on these topics is referred to textbooks on probability and statistics, as well as the following references: Seiler (1987), Iman and Helton (1988), Morgan and Henrion (1990), and DOE (1996). Instead, this Handbook presents a general discussion of the types of uncertainty that will be encountered in a regulatory analysis, primarily the value-impact portion, and outlines some of the more recent approaches to deal with them.

5.4.1 Types of Uncertainty

Vesely and Rasmuson (1984) identified seven categories of uncertainties in PRA, the majority of which, if treated at all, have only recently begun to receive attention. The seven categories are uncertainties in data, analyst assumptions, modeling, scenario completeness, accident frequencies, accident consequences, and interpretation. These seven categories, going from first to last, represent a progression from uncertainties in the PRA input to higher-level uncertainties with the PRA results. Vesely and Rasmuson considered these categories to be generally applicable to any modeling exercise, not just a PRA. Thus, they would also apply to the cost analysis portion of the regulatory analysis.

The first category, data uncertainty, is the most familiar and most often treated. It can be divided into four groups: population variation, imprecision in values, vagueness in values, and indefiniteness in applicability. Population variation refers to parameter changes from scenario to scenario, usually due to physical causes. The variations occur among the random variables which, when treated as constants, give a false impression of the stability of the results. Parameter imprecision and vagueness refer to separate concepts. Imprecision occurs when only limited measurements are available from which to estimate parameter values. Vagueness occurs when definitive values or intervals cannot be assigned to parameters. Indefinite applicability deals with the extrapolation of parameter values to situations different from those for which they were derived (e.g., extrapolating component failure data for normal environments to accident conditions).

The second category, analyst uncertainty, refers to variations in modeling and quantification which arise when different analysts perform different portions of the analysis. Often included with data uncertainty, analyst uncertainty provides its own separate contribution. Modeling uncertainty, the third category, arises from the indefiniteness in how comprehensive and how well characterized are the numerous models in the analysis. Do the models account for all significant variables? How well do the models represent the phenomena? Is the dependence between two phenomena accurately modeled? Similar to modeling uncertainty is completeness uncertainty, the fourth category. It differs only in that it occurs at the initial, identification stage in the analysis. When the analytic "boundaries" are drawn at the start of the analysis, how can one be sure that all "important" items have been included (e.g., the Three-Mile Island core-damage scenario was not specifically identified in PRAs until it had occurred)? Even if the important items have been included, are their interrelationships adequately defined (if even known)?

The last three uncertainty categories--those for accident frequencies and consequences, and interpretation--deal with the analytic output and results. Accident frequency uncertainties arise from two sources: variations between accidents of the same type and limited knowledge of the data, models, and completeness. Accident consequence uncertainties parallel those in accident frequency, except that they involve consequence modeling rather than frequency estimation. Interpretation uncertainty arises from the combination of all previous uncertainties plus the difficulty in conveying the information to the decision-maker. Even the most precise uncertainty analysis can be wasted if the meaning cannot be transferred to the decision-maker. Often, this results from difficulty in the way the results are presented. Ernst (1984) provides insight on reducing the uncertainty in interpretation of results.

5.4.2 Uncertainty Versus Sensitivity Analysis

As defined by Vesely and Rasmuson, uncertainty and sensitivity analyses are similar in that both strive to evaluate the variation in results arising from the variations in the assumptions, models, and data. However, they differ in approach, scope, and the information they provide.

Uncertainty analysis attempts to describe the likelihood for different size variations and tends to be more formalized than sensitivity analysis. An uncertainty analysis explicitly quantifies the uncertainties and their relative magnitudes, but requires probability distributions for each of the random variables. The assignment of these distributions often involves as much uncertainty as that to be quantified.

Sensitivity analysis is generally more straightforward than uncertainty analysis, requiring only the separate (simpler) or simultaneous (more complex) changing of one or more of the inputs. Expert judgment is involved to the extent that the analyst decides which inputs to change, and how much to change them. This process can be streamlined if the analyst knows which variables have the greatest effect upon the results. Variation of inputs one at a time is preferred, unless multiple parameters are affected when one is changed. In this latter case, simultaneous variation is required. Hamby (1993) provides a detailed description of the most common techniques employed in sensitivity analysis.

Vesely and Rasmuson identify which of the seven types of uncertainties encountered in PRAs are best handled by uncertainty versus sensitivity analysis. They are as follows:

1. Data Uncertainty: Use uncertainty analysis for population variation and value imprecision, sensitivity analysis for value vagueness and indefiniteness in applicability.

2. Analyst Uncertainty: Use sensitivity analysis.

3. Modeling Uncertainty: Use sensitivity analysis.

4. Completeness Uncertainty: Use sensitivity analysis.

5. Frequency Uncertainty: Use uncertainty analysis for variation from one accident to another, sensitivity analysis for the limited knowledge of the data, models, and completeness.

6. Consequence Uncertainty: Use uncertainty analysis for variation from one accident to another, sensitivity analysis for the limited knowledge of the data, models, and completeness.

7. Interpretation Uncertainty: Use sensitivity analysis.

5.4.3 Uncertainty/Sensitivity Analyses

Three major NRC studies involving detailed uncertainty/sensitivity analyses were NUREG-1150, *Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants* (NRC 1991); NUREG/CR-5381, *Economic Risk of Contamination Cleanup Costs Resulting from Large Non-Reactor Nuclear Material Licensee Operations* (Philbin et al. 1990); and NUREG/CR-4832, *Analysis of the LaSalle Unit 2 Nuclear Power Plant: Risk Methods Integration and Evaluation Program (RMIEP)* (Payne 1992). The first and third studies address reactor facilities, the second non-reactor facilities. The approach used in each study is summarized below.

5.4.3.1 NUREG-1150

"An important characteristic of the PRAs conducted in support of this report [NUREG-1150] is that they have explicitly included an estimation of the uncertainties in the calculations of core damage frequency and risk that exist because of incomplete understanding of reactor systems and severe accident phenomena." With this introduction, NUREG-1150 identified four steps in the performance of its uncertainty/sensitivity analysis:

1. Define the Scope. The total number of parameters that could be varied to produce uncertainty estimates was quite large and limited by computer capacity. Thus, only the most important sources were included, these sources being identified from previous PRAs, discussion with phenomenologists, and limited sensitivity analyses. For those parameters important to risk and having large uncertainties and limited, if any, data, subjective probability distributions were generated by expert panels.

2. Define Specific Uncertainties. Each section of the risk assessment was conducted at a slightly different level of detail, none of which to the degree involved in a mechanistic analysis. This resulted in the uncertain input parameters being "high level" or summary parameters, for which their relationships with their fundamental physical counterpart parameters were not always clear. This resulted in Vesely and Rasmuson's "modeling uncertainties." In addition, "data uncertainties" arose from limited knowledge of some important physical or chemical parameters. NUREG-1150 included both types of uncertainty, with no consistent effort to distinguish between them.

3. Define Probability Distributions. Probability distributions were developed by several methods, paramount among these being "expert elicitation" (discussed below). "Standard" distributions employed in previous risk assessments were used when the experts' estimation was not needed.

4. Combination of Uncertainties. The Latin hypercube method, a specialized form of stochastic simulation, was employed to sample from the various probability distributions. The sampled values were propagated through the constituent analyses to produce probability distributions for core damage frequency and risk. Results were presented graphically as histograms and complementary cumulative distribution functions showing the mean, median, and two-sided 90% confidence intervals.

A major innovation of the NUREG-1150 project was the development of a formal method for elicitation of expert judgment. Nine steps were involved:

1. Selection of Issues. The initial list of issues was identified from the important uncertain parameters specified by each plant analyst.

2. Selection of Experts. Seven expert panels were assembled to address issues in accident frequency (two panels), accident progression and containment loading (three panels), containment structural response (one panel), and source terms (one panel). Selection was based on recognized expertise in the nuclear industry, the NRC and its contractors, and academia. Each panel contained 3-10 experts.

3. Elicitation Training. Decision analysis specialists trained both the experts and analysis team members in elicitation methods, including the psychological aspects of probability estimation. The experts perfected their estimation techniques by conjuring probabilities for items for which "true" values were known.

4. Presentation and Review of Issues. The analysis staff formally presented the relevant issues to each panel over the course of several days. Interactive discussions ensued.

5. Preparation of Expert Analyses. Over a periods ranging from one to four months, each panel deliberated on its issues. However, each panel member arrived at his/her own quantitative results.

6. Expert Review and Discussion. At a final meeting, each expert presented his/her analysis which, in some cases, resulted in members modifying their preliminary results subsequent to the meeting.

7. Elicitation of Experts. Two analysis staff members, one trained in elicitation techniques, the other familiar with the technical subject, interviewed each expert privately. The expert's final quantitative results were documented.

8. Aggregation of Judgments. From each expert's results, the analysis staff composed probability distributions which were then aggregated to produce a single composite for each issue. Each expert was equally weighted in the composite.

9. Review by Experts. Each expert's probability distribution, as developed by the analysis staff from the expert's interview, was reviewed privately with that expert to correct any misconceptions that may have arisen. The probability distribution was then finalized, as was the composite.

5.4.3.2 NUREG/CR-5381

In NUREG/CR-5381, Philbin et al. took advantage of some of the convenient combinatorial properties of the lognormal distribution to facilitate a straightforward uncertainty analysis. NUREG/CR-5381 assessed the economic risk of cleanup costs resulting from non-reactor NRC licensee contamination incidents (see Section C.4). The calculational procedure involved three steps: estimating the frequency and cleanup cost of each accident scenario, taking their product to yield the "cleanup risk" (probabilistically-weighted cleanup cost) per scenario, and summing the scenario risks to yield the total facility risk. The uncertainty analysis paralleled these three steps.

For both the accident frequency and cleanup cost, probability distributions were selected from the available data, if possible, or by expert judgment. When using historical data to obtain frequency estimates, the assumption was made that the number of incidents for a specified scenario followed the Poisson distribution. This was deemed reasonable in light of the small number of incidents over a relatively large number of operating years and the absence of any obvious trends. The Poisson point estimate incident rate was taken to be the historical rate, with two-sided 80% confidence bounds derived from the properties of the Poisson distribution.

When a calculational model was used to estimate the frequency, the uncertainty was based on expert judgment. Unless deemed inappropriate, the frequency distribution was taken to be lognormal with an error factor of 10. If previous analyses provided only a frequency range, the distribution was again assumed to be lognormal, with the upper and lower bounds taken as the endpoints of this range. Thus, the point estimate (median, in this case) became their geometric mean. For the cleanup costs, the point estimates were derived from historical data of calculational models. These costs were assumed to be lognormally distributed with error factors of 1.25.

Philbin et al. defended their choice of the lognormal as a "generically" representative probability distribution for several reasons. The lognormal has a minimum value of zero, a realistic limit on the minimum frequency and cost, and is skewed in a way which yields relatively wider error bounds on the upper than lower side. Thus, it produces an uncertainty band which is conservative. Also, the lognormal has two convenient combinatorial properties. The product of two lognormally distributed variables is lognormally distributed, while the sum can be approximated by another lognormal provided one variable dominates the other.

The economic risk per accident scenario was estimated by propagating the frequency and cost uncertainties through their product. When both frequency and cost were lognormally distributed, this product was also lognormal. When the frequency distribution was Poisson, it was approximated by a lognormal to simplify the calculation. Each scenario thus resulted in an economic risk which was lognormally distributed. These were summed to yield the total economic risk per facility. The individual variances were summed and the resultant total economic risk was assumed to be approximately lognormal, a reasonable assumption if it was dominated by one scenario risk. Referring to Tables C.4-C.8 in Section C.4, one can see that this assumption was generally valid for three of the five facilities (i.e., one scenario risk contributed over 50% to the total facility risk). The final results were reported as two-sided 80% confidence bounds.

5.4.3.3 NUREG/CR-4832

In NUREG/CR-4832, Payne generally followed an uncertainty/sensitivity calculational procedure similar to that employed in NUREG-1150. The major contribution was the development of a new computer code, TEMAC (Iman and Shortencarier 1986) to perform the final quantification of the accident sequence uncertainties via the Latin hypercube sampling method. The TEMAC code also calculated various risk importance measures (Vesely et al. 1983) and ranked the basic events by their contribution to mean core damage frequency.

Three importance measures were estimated in NUREG/CR-4832. The first, risk reduction importance, calculates the decrease in the total core damage frequency which could result if a single basic event's probability were set to zero (i.e., the component could not fail or the event could not occur). The second, risk increase importance, calculates the increase in the core damage frequency which could result if a single basic event's probability were set to one (i.e., the component would always fail or the event would always occur). The third, uncertainty importance, estimates the extent to which the uncertainty in the total core damage frequency depends upon the underlying uncertainty in a common contributor to a set of related basic events (e.g., a failure to actuate in all motor-operated valves). These importance measures represent a combination of sensitivity with uncertainty analyses which feature some of the better aspects of each.

5.4.4 Suggested Approach

The value-impact portion of a regulatory analysis will often require use of an existing risk assessment for the estimation of some of the attributes. If the risk assessment has an uncertainty/sensitivity analysis accompanying it, the analyst should try to adapt it for use in the value-impact analysis. Unfortunately, this is often impractical for the standard analysis since the analyst does not have access to the computer code and numerous data and assumptions necessary to generate the resultant probability distributions.

When a detailed uncertainty/sensitivity analysis is not possible or practical, the following approach is suggested for the standard analysis. The standard analysis should attempt to include an uncertainty/sensitivity analysis approaching the level of that conducted by Philbin et al. in NUREG/CR-5381 (see Section 5.4.3.2). This analysis can be done with varying degrees of formality and rigor. First, a systematic attempt should be made to identify all of the pertinent factors (assumptions, data, models) that could affect the results. Since the number of such factors is usually very large, not all of them can be treated in detail. Nevertheless, it is useful to make a systematic effort at least to identify them. As a second step, the list of factors should be screened to select a subset for detailed examination. The screening process should concentrate on eliminating unimportant factors (for example, those that are known to contribute little to the overall uncertainty or those that have minimal effect on the bottom line results) and reducing the list to manageable size. Typically, the screening will be done on the basis of judgment and experience, but more formal methods and calculations may be appropriate in some circumstances (e.g., an abridged form of the "expert elicitation" procedure in NUREG-1150 [see Section 5.4.3.1]). The third step is to define a set of cases to be evaluated. The most common approach is to define a best estimate, establish a range of interest for each factor, and then systematically vary the factors, one or more at a time. The results are then expressed as a range (low value, best estimate, high value) which indicates the effect on the output of variations in the factors, and thus provides some insight concerning uncertainties and their effects.

Uncertainty/sensitivity analysis for the cost measures is generally simpler than that for exposures. Complex accident scenarios are not involved. Moreover, the analyst usually has a better "feel" for cost-related measures (e.g., labor rates, interest rates, and equipment costs) than for risk-related ones. Thus, such analyses require no more than the straightforward variation of interest rates, labor hours, contingency factors, etc. However, the analyst is cautioned that, while the calculational techniques may be simple, wide ranges can still result.

To assist the analyst in performing uncertainty/sensitivity analyses for the standard analysis, this Handbook provides high and low values for selected best estimates in the evaluation of certain attributes (see, for example, Section 5.7.3.1). Should the analyst have access to better estimates, they should be used. In the cases where the analyst has access to a computerized assessment, the uncertainty/sensitivity analysis results obtainable via computer can be incorporated into the standard analysis. However, it is felt that more formal uncertainty/sensitivity analyses will only be practical for regulatory analyses requiring major efforts.

Finally, automated uncertainty calculations using default distributions are a feature of the FORECAST computer code for regulatory effects cost analysis (Lopez and Sciacca 1996). Uniform, lognormal, and several user-specified probability distributions are options.

ATTACHMENT 3 - COMPARISON OF NRC'S EXISTING GUIDANCE ON THE TREATMENT OF UNCERTAINTY AND THE SAFE DRINKING WATER ACT INFORMATION QUALITY STANDARDS

(1) OMB -" specify, to the extent practicable (i) each population addressed by any estimate [of applicable risk effects]."

NRC guidance accomplishes this at two levels. First, it is mandatory to separately quantify and present risk effects (adverse health, environmental and economic) for both the general public and the licensee. The relevant attributes explicitly identified by the NRC include public radiation exposure, occupational radiation exposure, averted onsite impacts (licensee property), and averted offsite property damage (non-licensee property which includes environmental clean-up, losses of animals, food stuff, etc) (see RAG,p.23). Detailed guidance on the quantification of these consequences is discussed in the RATEH (public health (accident), pp.5.22-5.27; occupational Health (accident), pp.5.29-5.34; offsite property, pp.5.37 -5.40; and onsite property, pp.5.40-5.49).

In addition, both NRC documents make clear that it is desirable to consider consequences in terms of the different groups that may be affected by a proposed action and that such differentiation is not limited to the set of attributes identified above (RAG, p.21). Thus, for example, if a given regulatory issue had a disproportionate affect on a sub-class of the general population (e.g. radiation exposure to children), than the consequences to that class should be addressed separately.

(2) OMB - "specify, to the extent practicable (ii) the expected risk or central estimate of risk for the specific populations [affected]";

In addition to attachments 1 and 2, which provide policy and guidance concerning uncertainty in risk estimation, the following passage from p. 4.7 of the RATEH captures most succinctly, this concern for providing measures of central value:

> Section 4.3 of the Guidelines requires the use of best estimates. Often these are evaluated in terms of **expected value** [emphasis added], the product of the probability of some event occurring and the consequences which would occur assuming the event actually happens. Sometimes, measures other than the expected value may be appropriate, such as the mean, median, or other point estimate. However the expected value is generally preferred.

(3) OMB - "specify, to the extent practicable (iii) each appropriate upper-bound or lower-bound estimate of risk"

NRC guidance recognizes the importance of addressing the variability/ dispersion associated with a central measure of risk, and Attachments 1 and 2 speak directly to this point. In the RATEH (attachment 2) the discussion focuses on the use of uncertainty and sensitivity analyses. Either approach can generate upper and lower bound estimates of risk. The actual method relied upon is typically influenced by data and model needs, as well as practical considerations concerning the level of importance and controversial nature of the proposed regulatory action.

Uncertainty analysis is described as the more formalized procedure and is characterized as a methodology to determine statistical values such as **"upper and lower bounds"** on parameters of interest [emphasis added] (RATEH, p.5.3).

Sensitivity analysis tends to be a more straightforward approach which allows for the separate or simultaneous changing of key inputs. When one simultaneously changes all relevant inputs, one can obtain upper and lower bound estimates of risk as well.

(4) OMB -"specify, to the extent practicable (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty"

With respect to the specification of each significant uncertainty associated with the risk assessment, the RATEH identifies seven categories of uncertainty that are relevant to NRC uncertainty/sensitivity analyses. These are: data; analyst; modeling completeness, frequency; consequence; and interpretation. To the extent practicable and appropriate, the NRC analyst would be expected to consider and address all significant specific elements of uncertainty from within these seven categories. A discussion of these types of uncertainty appear in section 5.4.1 of Attachment 2.

With respect to specific studies that would assist in resolving the uncertainty, the NRC actively pursues many activities towards this end. For example, research funding on the overall state-of-the-art of probabilistic risk assessment (PRA) technology is a continuous on-going effort, and the individual plant evaluation (IPE) program helps to ensure that the latest PRA techniques are applied to current data and most recent design changes. These updated studies clearly help to resolve some of the uncertainty embedded in NRC’s risk assessments.

In addition, NRC devotes resources towards improving its estimation capabilities concerning the consequences of an accident, recognizing that these uncertainties are also important in the risk equation. Towards this end, for example, the NRC is currently funding work on refining MACCS (MELCOR Accident Consequence Code Systems), a consequence code that evaluates a full spectrum of the offsite consequences of an accident.

(5) OMB - "specify, to the extent practicable (v) peer reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data"

A large number of the risk studies that are of concern to the NRC have been and continue to be developed with direct involvement by the NRC. These studies are typically subject to rigorous quality control practices when initially developed and again when they are used to support regulatory decisions. Peer review is an integral part of this process. For example, internal peer review groups likely to be involved include the Committee For Review of Generic Requirements, Probabilistic Risk Assessment Steering Committee, and the Risk-Informed Licensing Panel. In addition, research products are typically subject to independent peer review, and when used in regulatory decision-making are subject to additional independent review by relevant advisory committees (Advisory Committee on Reactor Safeguards (ACRS), Advisory Committee on Nuclear waste (ACNW), and Advisory Committee for Medical Use of Isotopes (ACMUI).

Furthermore, NRC regulatory analysis guidance strongly supports reliance on peer reviewed, state of the art analyses. Towards this end, the RATEH has sought out the most reputable analyses and sources of data and incorporated that information directly into the Handbook. In this way, the NRC attempts to ensure consistent, high quality regulatory analyses.

(6) OMB - Summary Characterizations

1. comprehensive, informative and understandable
2. best available studies and data

Key objectives of NRC's regulatory analysis process include the development and presentation of an analysis that is ... "clear and well documented" ..... " open and transparent" ...... "based on adequate information", and ... "documented with sufficient detail to enable the analysis to be repeated" (see RAG, pp.1 and 12). Clearly, NRC's commitment to these attributes ensures that its treatment of risk and uncertainty will be comprehensive, informative and understandable. Furthermore, the preceding discussions are also supportive of these summary characterizations, as, for example, section (5) speaks directly to the use of best available studies and data.